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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,516	08/01/2001	Loretta Itri	ORT-1462	6089

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EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/921,516	ITRI ET AL.	
	Examiner	Art Unit	
	Karen A Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *7-19 and 23-28* is/are withdrawn from consideration.

5)☐ Claim(s) *20-22* is/are allowed.

6)☐ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

☐ Notice of References Cited (PTO-892)

☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/3/01+1/31/02*.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

1. Acknowledgment is made of Applicant's election of the species of nucleoside analogs, within the context of the claimed method of treatment. As stated in the previous Office action, upon allowance of the generic claims, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise included all the limitations of said generic claim.

2. Claim 1-28 are pending. Claims 7-19, 23-28, drawn to non-elected species, are withdrawn from consideration at this time. Claims 1-6 and 20-22 are examined on the merits.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Silvestris et al (Int J Clin Lab Res 1995, Vol. 25, pp. 79-83, reference of the IDS submitted December 3, 2001). Claim 1 is drawn to a method comprising administering an interferon dosing regiment to a subject in need thereof and administering a therapeutically effective amount of EPO to the subject, wherein the EPO improves the ability to the subject to maintain or increase the interferon dosing regiment. Claim 2 embodies the method of claim 1 wherein the interferon dosing regimen is administered as a single therapeutic agent.

Silvestris et al disclose a methods of treating multiple myeloma comprising administering an interferon dosing regimen comprising alpha-IFN and administering recombinant human EPO (page 79, second column, lines 14-19). Silvestris et al disclose that alpha-IFN arrests the maturation of malignant plasma cells at the G0-G1 level (page 79, second column, lines 24-28).

Silvestris et al disclose that combined treatment of multiple myeloma patients with alpha IFN and EPO restores normal B-cell function and that this effect was particularly evident in several multiple myeloma patients with complete remission and receiving long-term combined treatment with EPO and alpha-IFN (page 82, first column, lines 2-5 under the heading "Discussion"). Silvestris et al disclose that normal B-cell function is persistently depressed in patients with progressing multiple myeloma (page 82, second column, last paragraph, lines 4-7). Silvestris et al conclude that because alpha-IFN down-regulates B-cell proliferation in multiple myeloma, restoration of normal IgG secretion is attributed to EPO and may be the result of a synergistic effect of EPO with alpha-IFN (page 83, first column, lines 11-14), thus fulfilling the specific embodiment of claim 1 specifying that the EPO improves the ability of the subject to increase or maintain the interferon dosing regimen. It would be inherent in the patients undergoing long-term combined treatment with EPO and alpha-IFN that the restoration of normal B-cell function improves said patients ability to maintain the interferon dosing regimen because said individuals will have normal B-cell function and will be less susceptible to infectious disease during the long-term treatment.

5. Claims 1 and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by the abstract of Weis et al (Abstract H-156, ICAAC, September 24-27, 1998, reference of the IDS submitted December 3, 2001).

The specific embodiments of claim 1 is set forth above. Claim 3 embodies the method of claim 1 wherein the interferon dosing regimen comprises the administration of interferon concurrently with a nucleoside analog. Claim 4 embodies the method of claim 3 wherein the nucleoside analog is selected from a group consisting of ribavirin. Claim 5 embodies the method of claim 4 wherein the nucleoside analog is ribavirin and the interferon dosing regimen is administered to a subject having chronic hepatitis C.

The abstract of Weiss et al discloses a method of treating subjects having chronic hepatitis C without HIV infection comprising administering an interferon dosing regimen comprising ribovirin and alpha-IFN. The abstract discloses that administration of EPO to patients developing anemia as a result of the ribovirin/alpha-IFN therapy resulted in an increase of hemoglobin and that the symptoms resolved at a more rapid rate than the increase in

hemoglobin alone would indicate. The abstract fulfills the specific embodiment of claim 1 specifying that the EPO improves the ability of the subject to increase or maintain the interferon dosing regimen because the administration of EPO eliminates the necessity of decreasing the ribavirin of the interferon dosing regimen.

6. Claims 1 and 3-6 are rejected under 35 U.S.C. 102(a) as being anticipated by the abstract of Dieterich et al (Abstract H-156, ICAAC, September 26-29, 1999, reference of the IDS submitted December 3, 2001)

The specific embodiments of claims 1 and 3-5 are set forth above. Claim 6 embodies the method of claim 4 wherein the nucleoside analog is ribavirin and the interferon dosing regimen is administered to a subject fort he treatment of chronic hepatitis C and the subject is also infected with HIV.

The abstract of Dieterich et al discloses a method of treating subjects having chronic hepatitis C wit HIV infection comprising administering an interferon dosing regimen comprising ribovirin and alpha-IFN. The abstract discloses that administration of EPO to patients successfully treated anemia resulting from ribovirin treatment.

7. Claims 20-22 are free of the art.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.
9/20/2004

KAREN A. CANELLA PH.D
PRIMARY EXAMINER